



Food and Drug Administration
10903 New Hampshire Avenue
Building 66
Silver Spring, MD 20993

Dear Panel Member,

Thank you for agreeing to participate in the General and Plastic Surgery Devices Panel to discuss post-approval studies for silicone gel-filled breast implants. My name is James Swink, and I am the Designated Federal Officer for the FDA/CDRH General and Plastic Surgery Devices Advisory Panel. This background information is for your use during deliberations at the upcoming Panel meeting August 30 and 31, 2011. Please do not discuss this information with members of the press or public, with financial institutions, or with any other person, including other Panel members. If for any reason you are contacted by anyone seeking to obtain or discuss this information, please refrain from any discussion of it and the meeting and advise me of this immediately.

The only publicly available information on the meeting agenda is the meeting topic. Two business days before the meeting, the meeting agenda, the roster, and FDA's executive summary and questions will be posted on the FDA website. If you require additional information, please contact me. If you believe you may have any conflict of interest for the meeting topic, please refrain from reviewing this information until Committee Management's Ms. Margaret Ames informs you via e-mail that you are cleared for the meeting. Please be advised that your travel arrangements will be made by Denise Vitale in our Committee Management office Tryphena.Vitale@fda.hhs.gov.

After the meeting is adjourned, please leave this CD at your place on the Panel table for document tracking. After the meeting, the 24 hour summary, transcript, and summary minutes will be posted at the Panel meeting web site.

If you have any questions or concerns, or if I can be of assistance to you in any way regarding the Panel meeting agenda or logistics, please let me know. I may be reached at 301-796-6313 or via e-mail at james.swink@fda.hhs.gov.

Thank you for agreeing to share your expertise with us. I look forward to working with you and having a productive meeting.

Sincerely,

James Paul Swink
Designated Federal Officer
Medical Devices Advisory Committee
Center for Devices and Radiological Health
James.Swink@fda.hhs.gov
Phone: 301-796-6313